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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/265,191	03/10/99	CARSON	D 07340/044002

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EXAMINER

NGUYEN, Q

ART UNIT	PAPER NUMBER
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1632

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DATE MAILED:

09/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/265,191

Applicant(s)

CARSON ET AL.

Examiner

Quang Nguyen, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 30days MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-176 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claims 85-176 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some * c) ☐ None of the CERTIFIED copies of the priority documents have been:
1. ☐ received.
2. ☐ received in Application No. (Series Code / Serial Number) ____.
3. ☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 18) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

DETAILED ACTION

The preliminary amendment filed 28 July 2000 has been entered. Claims 1-84 filed in the preliminary amendment dated 21 April 1999 have been cancelled. Per 35 CFR 1.126, claims 124-215 in the preliminary amendment filed 28 July 2000 have been renumbered as claims 85-176. Claims 85-176 are now pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims (87, 88, 91, 92), (110, 111, 114, 115), (133, 134, 137, 138) and (156, 157, 160, 161), drawn to methods of reducing antigen-stimulated IgE production in a mammal, for treating an antigen-stimulated IgE-related disorder in a mammal, for stimulating production of Th1 lymphocytes in a mammal, for suppressing production of Th2 lymphocytes in a mammal, respectively, comprising administering an immunostimulatory polynucleotide (ISS-PN) to a mammal sensitized to an antigen, wherein the ISS-PN comprises the sequence 5'cytosine, guanine-3', and wherein the same method further comprises co-administering the antigen in the form of a polynucleotide to the mammal, classified in class 514, subclass 44, for example.
- II. Claims (89, 90), (112, 113), (135, 136) and (158, 159), drawn to methods of reducing antigen-stimulated IgE production in a mammal, for treating an

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antigen-stimulated IgE-related disorder in a mammal, for stimulating production of Th1 lymphocytes in a mammal, for suppressing production of Th2 lymphocytes in a mammal, respectively, comprising administering an immunostimulatory polynucleotide (ISS-PN) to a mammal sensitized to an antigen, wherein the ISS-PN comprises the sequence 5'cytosine, guanine-3', and wherein the same method further comprises co-administering the antigen in the form of a polypeptide to the mammal, classified in class 514, ~~subclass 44~~, subclass 2, for examples.

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Claims (85, 86, 93-107), (108, 109, 116-130), (131, 132, 139-153) and (154, 155, 162-176) drawn to methods of reducing antigen-stimulated IgE production in a mammal, for treating an antigen-stimulated IgE-related disorder in a mammal, for stimulating production of Th1 lymphocytes in a mammal, for suppressing production of Th2 lymphocytes in a mammal, respectively, classified in class 514, subclass 44 will be examined with the elected group.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups I and II are directed to methods that are distinct both physically and are not required one for the other. Invention I requires the co-administering an antigen in the form of a polynucleotide to the mammal, whereas in Invention II said antigen is in the form of a

polypeptide. The polynucleotide used in the method of Invention I is made up of nucleotides and the polypeptide used in the method of Invention II is composed of amino acid residues, and said polynucleotide and said polypeptide are not required of each other. Therefore, a search and examination of both methods in one patent application would result in an undue burden, since the searches for both methods are not co-extensive, the classification is different, and the subject matter is divergent.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17 (h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (703) 308-8339.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, J.D., may be reached at (703) 305-6608.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-2801.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1632.

Papers related to this application may be submitted to Group 160 by facsimile transmission. Papers should be faxed to Group 160 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014 or (703) 308-4242.

Quang Nguyen, Ph.D.

Examiner, AU 1632

Karen M. Hauda
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